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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,411	04/11/2002	Paul Simmons	A20-033	9003

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EXAMINER	
BELYAVSKYI, MICHAIL A	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 01/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/030,411	SIMMONS ET AL.	
	Examiner	Art Unit	
	Michail A. Belyavskyi	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-28,31,34,40-45 and 47-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-28,31,34,40-45 and 47-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 08/15/05 is acknowledged.

Claims 25-28,31,34, 40-45 and 47-58 are pending.

In view of the amendment, filed 08/15/05 the following rejections remain:

2. The following is a quotation of the second paragraph of 35 U.S.C. 112.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 26, 27 and 53- 58 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 is indefinite and ambiguous in the recitation of "6-19" , line 5, as a surface marker specific for mesenchymal precursor cells. The characteristics and metes and bounds of the term "6-19" as a surface marker specific for mesenchymal precursor cells is unclear and indefinite.

Applicant's arguments, filed 08/15/05 , have been fully considered, but have not been found convincing.

Applicant asserts that recitation of the marker "6-19" would be clearly understood by a person of skilled in the art and provides a that copies of prior art to support his position.

It is noted that no copies of said prior art have been provided.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 26 stands rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a New Matter rejection.**

6. "...surface markers specific for mesenchymal precursor cells consisting of any combination thereof" claimed in claim 26 represent a departure from the specification and the claims as originally filed. The passage pointed by the applicant do not provide a clear support for "surface markers specific for mesenchymal precursor cells consisting of any combination thereof".

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:
A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 25-28, 31, 34, 40, 41, 44, 48, 49 and 52-58 are rejected under 35 U.S.C. 102(b) as being anticipated by Simmons et al., (IDS,) for the same reasons set forth in the previous Office Action, mailed on 06/28/05.

Applicant's arguments, filed 08/15/05 have been fully considered, but have not been found convincing.

Applicant asserts that : (i) the present invention represents an important advance over the Simmons et al., disclosure because it is based on the identification of a subpopulation within the fraction of STRO-1 positive cells, that can be also identified by the VCAM-1 marker; (ii) inherently only less than 1% of Stro-1 positive cells disclosed by Simmons et al., are capable of giving rise to CFU-F, as evidenced from Fig.9 of the instant application.

Contrary to Applicant's assertion, it is the Examiner position, Simmons et al., teach an enriched cell population of mesenchymal precursors cells that are capable of giving rise to CFU-F and composition comprising said cells (see entire document, page 272 and Fig.2 in particular). Simmons et al., teach that said enriched cell population carry the antigen identified by STRO-1 antibody and that said cells **are also positive for VCAM, LFA-3, THY-1, P-selectin, L-selectin, CD49b/CD29 surface markers (see Table 1 in particular).** Simmons et al., teach that said cells are capable of differentiation into at least adipocytes, osteoblasts and fibroblast (see Fig.1 in particular). Although the reference is silent about that said enriched cell population of mesenchymal precursors comprises at least 1%, 5%, 10% or 40 % of cells capable of giving rise to CFU-F, as recited in claims 25-28, 31and 34 or that composition comprising said cells also includes hemopoietic cells, as claimed in claim 49, or that said cell population are positive

for CD146 or STRO-2, as claimed in claims 56 and 57 ; or that SRTO-1 ^{bright} cells are negative for at least one marker as recited in claim 58, these limitation would be inherent properties of the referenced cell composition because the referenced cell composition was obtained by the same method as claimed. Since the office does not have a laboratory to test the reference enriched cell population, it is applicant's burden to show that the reference cell population does not have the same properties as recited in the claims. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983); *In re Fitzgerald et al.*, 205 USPQ 594 (CCPA 1980).

With regards to the issue that "inherently only less than 1% of Stro-1 positive cells disclosed by Simmons et al., are capable of giving rise to CFU-F, as evidenced from Fig.9 of the instant application." It is noted that Applicant himself acknowledge that the instant applications is further identification of a subpopulation within the fraction of STRO-1 positive cells disclosed by Simmons. Moreover, Applicant uses similar fractions of Srto-1 positive cells as Simmons et al., to enrich cell population for cells capable giving raise to CFU-F.

Claims 41, 44 , 48 and 49 are included because the claimed functional limitation would be inherent properties of the referenced enriched cell population and composition comprising said cells. A cell population and composition comprising said cells is cell population and composition comprising said cells irrespective of their intended use in the absence of evidence of structural difference.

The reference teaching anticipates the claimed invention.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 25, 45 and 47 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Simmons et al (IDS) in view of US Patent 6,087113 as is evidenced by the disclosure of the instant Specification on page 16, lines 20-30 for the same reasons set forth in the previous Office Action, mailed on 06/28/05.

Applicant's arguments, filed 08/15/05 have been fully considered, but have not been found convincing.

Applicant asserts that since Simmons et al., does not teach the instant invention, it can not be used in combination with the secondary reference for obviousness rejection.

Contrary to Applicant's assertion, as has been discussed supra, it is the Examiner position, that Simmons et al., is a prior art reference and thus can be used for obviousness rejection.

The teaching Simmons et al., has been discussed, supra.

The claimed invention differs from the reference teaching in that the Simmons et al., do not explicitly teach a composition comprising an enriched cell population of cells capable of giving rise to CFU-F, that are preadsorbed onto ceramic vehicles and are suitable for implantation to augment bone marrow transplantation, as claimed in claim 47.

Simmons et al., further teach that enriched population of progenitor cells capable of giving rise to CFU-F can be used in treatment various disorders of the hematopoietic system.

US Patent '113 teaches a composition wherein the mesenchymal precursor cells are preadsorbed onto ceramic vehicles that are suitable for implantation to augment bone marrow transplantation (see column 9, lines 8-15, column 14, lines 15-25 and Example 7 in particular). Although the reference is silent that ceramic vehicles were precoated with fibronectin, it is noted that US Patent '113 teaches that said ceramic vehicles were pretreated as previously disclosed, by referenced to the inventors previous publication by Caplan et al (see column 14, lines 12-30) . As disclosed in the instant Specification on page 16, lines 20-30, the ceramic vehicles were pre-treated with fibronectin as reported by Caplan et al. Thus, ceramic vehicles disclosed by US Patent '113 would be inherently precoated by the same method as recited in the instant claim, i.e. with fibronectin.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply the teaching of US Patent '113 to those of Simmons et al., to obtain a claimed composition comprising an enriched cell population of cells capable of giving rise to CFU-F, that are preadsorbed onto ceramic vehicles and are suitable for implantation to augment bone marrow transplantation.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so, because a composition comprising a ceramic vehicles with preadsorbed mesenchymal progenitor cells can be used for correction or modifying connective tissue disorder or enhancing the implantation as taught by US Patent '113. The referenced cells taught by US Patent '113 by can be substitute by the cells taught by Simmons et al., to generate a composition comprising population of cells capable of giving rise to CFU-F, that are preadsorbed onto ceramic vehicles and are suitable for implantation . The strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. In re Semaker. 217 USPQ 1, 5 - 6 (Fed. Cir. 1983). See MPEP 2144.

From the combined teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

11. Claims 25, 42, 43, 45, 50 and 51 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Simmons et al (IDS) in view of US Patent 5,591,625 for the same reasons set forth in the previous Office Action, mailed on 06/28/05.

Applicant's arguments, filed 08/15/05 have been fully considered, but have not been found convincing.

Applicant asserts that since Simmons et al., does not teach the instant invention, it can not be used in combination with the secondary reference for obviousness rejection.

Contrary to Applicant's assertion, as has been discussed supra, it is the Examiner position, that Simmons et al., is a prior art reference and thus can be used for obviousness rejection.

The teaching Simmons et al., has been discussed, supra.

Simmons et al further teach that mesenchymal precursors cells that are capable of giving rise to CFU-F are ideal target for gene therapy and may provide a means of treating disorders of the hemopoietic system (see page 278 in particular).

The claimed invention differs from the reference teaching in that Simmons et al., does not explicitly teaches an enriched cells population wherein said cells are capable of giving rise to CFU-F or a composition comprising said cells wherein said cells has an exogenous nucleic acid

transformed in to it, as claimed in claims 42 or 50 or wherein said cells has an exogenous nucleic acid that express a therapeutic agent transformed in to it, as claimed in claims 43 or 51 .

US Patent ' 625 teaches genetically engineered human mesenchymal stem and progenitor cells that have been transformed with exogenous nucleic acid that expresses a therapeutic agent (see entire document, overlapping column 1 and 2 in particular). US Patent' 625 teaches that said cells can be used to treat various diseases including genetic disorders, diseases of bone and cartilage and bone marrow or to be use to release of therapeutics (see column 2, lines 1-65 in particular).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply the teaching of US Patent '625 to those of Simmons et al., or US Patent '113 to obtain a claimed an enriched cells population wherein said cells are capable of giving rise to CFU-F or a composition comprising said cells wherein said cells has an exogenous nucleic acid transformed in to it or wherein said cells has an exogenous nucleic acid that express a therapeutic agent transformed in to it.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so, because a genetically engineered human mesenchymal stem and progenitor cells that have been transformed with exogenous nucleic acid that expresses a therapeutic agent can be used to treat various diseases including genetic disorders, diseases of bone and cartilage and bone marrow or to be use to release of therapeutics as taught by US Patent '625 . Said cells can be substituted by the cells taught by Simmons et al., because mesenchymal precursors cells that are capable of giving rise to CFU-F are ideal target for gene therapy and may provide a means of treating disorders of the hemopoietic system human mesenchymal progenitor cells that are used to treat diseases, for example of the hematopoietic system as taught by Simmons et al., The strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. In re Semaker. 217 USPQ 1, 5 - 6 (Fed. Cir. 1983). See MPEP 2144.

From the combined teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 25-28, 31, 34, 40, 41, 44, 48, 49 and 52-58 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1- 39 and 68- 78 of copending Application No. 10/813747. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1- 39 and 68- 78 of copending Application No. 10/813747 recited an enriches cell population of mesenchymal precursor cells, co-expressing STRO-1 and VCAM-1, wherein at least 1% of the cells capable of forming a clonogenic colony and are SRO-1 ^{bright} (see claims 6, 7, 25-30 and 68-74 in particular), or capable of differentiation into at least two commited cell types (see claims 31 and 75 in particular). Although the reference claims are silent about that said enriched cell population of mesenchymal precursors or composition comprising said cells also includes hemopoietic cells, as claimed in claim 49, or that said cell population are positive for CD146 or STRO-2, as claimed in claims 56 and 57 ; or that SRTO-1 ^{bright} cells are negative for at least one marker as recited in claim 58, these limitation would be inherent properties of the referenced cell composition because the referenced cell composition was obtained by the same method as claimed. Since the office does not have a laboratory to test the reference enriched cell population, it is applicant's burden to show that the reference cell population does not have the same properties as recited in the claims. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983); *In re Fitzgerald et al.*, 205 USPQ 594 (CCPA 1980).

Claims 41, 44 , 48 and 49 are included because the claimed functional limitation would be inherent properties of the referenced enriched cell population and composition comprising said cells. A cell population and composition comprising said cells is cell population and composition comprising said cells irrespective of their intended use in the absence of evidence of structural difference.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments, filed 08/15/05 have been fully considered, but have not been found convincing.

Applicant submits that it is appropriate to address this issue in copending Application No. 10/813747 and file a terminal disclaimer in the '747 application, rather than address that rejection in the instant application.

Given applicant's statements concerning the applicability of the obvious double patenting rejection, it appears that applicant has acquiesced to the appropriateness of the double patenting rejection and only requests that the instant application be allowed to issue.

However, in contrast to applicant's presumptions, the instant application is not considered allowable at this time.

Therefore the double patenting rejection stands for the claims of the instant application.

13. Claims 25, 45 and 47 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1- 39 and 68- 78 of copending Application No. 10/813747 in view of US Patent 6,087113 as is evidenced by the disclosure of the instant Specification on page 16, lines 20-30 .

The teachings of claims 1- 39 and 68- 78 of copending Application No. 10/813747 has been discussed supra.

Claims 1- 39 and 68- 78 of copending Application No. 10/813747 do not explicitly recites a composition comprising an enriched cell population of cells capable of giving rise to CFU-F, that are preadsorbed onto ceramic vehicles and are suitable for implantation to augment bone marrow transplantation.

US Patent '113 teaches a composition wherein the mesenchymal precursor cells are preadsorbed onto ceramic vehicles that are suitable for implantation to augment bone marrow transplantation (see column 9, lines 8-15, column 14, lines 15-25 and Example 7 in particular). Although the reference is silent that ceramic vehicles were precoated with fibronectin, it is noted that US Patent '113 teaches that said ceramic vehicles were pretreated as previously disclosed, by referenced to the inventors previous publication by Caplan et al (see column 14, lines 12-30) . As is evidenced from the disclosure of the instant Specification on page 16, lines 20-30 the ceramic vehicles were pre-treated with fibronectin as reported by Caplan et al. Thus ceramic vehicles disclosed by US Patent '113 would be precoated with fibronectin.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply the teaching of US Patent '113 to those of claims 1- 39 and 68- 78 copending Application No. 10/813747 to obtain a claimed composition comprising an enriched cell population of cells capable of giving rise to CFU-F, that are preadsorbed onto ceramic vehicles and are suitable for implantation to augment bone marrow transplantation.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so, because a composition comprising a ceramic vehicles with preadsorbed mesenchymal progenitor cells can be used for correction or modifying connective tissue disorder or enhancing the implantation or as taught by US Patent '113. The referenced cells are the same cells as taught by claims 1- 39 and 68- 78 thus the cells taught by US Patent '113 can be substitute by the cells taught by claims 1- 39 and 68- 78 to generate a composition comprising population of cells capable of giving rise to CFU-F, that are preadsorbed onto ceramic vehicles and are suitable for implantation . The strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. In re Semaker. 217 USPQ 1, 5 - 6 (Fed. Cir. 1983). See MPEP 2144.

From the combined teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments, filed 08/15/05 have been fully considered, but have not been found convincing.

Applicant submits that it is appropriate to address this issue in copending Application No. 10/813747 and file a terminal disclaimer in the '747 application, rather than address that rejection in the instant application.

Given applicant's statements concerning the applicability of the obvious double patenting rejection, it appears that applicant has acquiesced to the appropriateness of the double patenting rejection and only requests that the instant application be allowed to issue.

However, in contrast to applicant's presumptions, the instant application is not considered allowable at this time.

Therefore the double patenting rejection stands for the claims of the instant application.

14. Claims 25, 42, 43, 45, 50 and 51 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1- 39 and 68-78 of copending Application No. 10/813747 in view of US Patent 5,591,625.

The teachings of claims 1- 39 and 68- 78 of copending Application No. 10/813747 has been discussed supra.

Claims 1- 39 and 68- 78 of copending Application No. 10/813747do not explicitly recited an enriched cells population wherein said cells are capable of giving rise to CFU-F or a composition comprising said cells wherein said cells has an exogenous nucleic acid transformed in to it, as claimed in claims 42 or 50 or wherein said cells has an exogenous nucleic acid that express a therapeutic agent transformed in to it, as claimed in claims 43 or 51 .

US Patent ' 625 teaches genetically engineered human mesenchymal stem and progenitor cells that have been transformed with exogenous nucleic acid that expresses a therapeutic agent (see entire document, overlapping column 1 and 2 in particular). US Patent' 625 teaches that said cells can be used to treat various diseases including genetic disorders, diseases of bone and cartilage and bone marrow or to be use to release of therapeutics (see column 2, lines 1-65 in particular).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply the teaching of US Patent '625 to claims 1- 39 and 68- 78 of copending Application No. 10/813747 to obtain a claimed an enriched cells population wherein said cells are capable of giving rise to CFU-F or a composition comprising said cells wherein said cells has an exogenous nucleic acid transformed in to it or wherein said cells has an exogenous nucleic acid that express a therapeutic agent transformed in to it.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so, because a genetically engineered human mesenchymal stem and progenitor cells that have been transformed with exogenous nucleic acid that expresses a therapeutic agent can be used to treat various diseases including genetic disorders, diseases of bone and cartilage and bone marrow or to be use to release of therapeutics as taught by US Patent '625 . Said cells can be substituted by the cells recited by claims 1- 39 and 68- 78 of copending Application No. 10/813747 since both referenced and recited cells are human mesenchymal progenitor cells that can be used to treat various diseases including genetic disorders, diseases of bone and cartilage and bone marrow. The strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. In re Semaker. 217 USPQ 1, 5 - 6 (Fed. Cir. 1983). See MPEP 2144.

From the combined teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments, filed 08/15/05 have been fully considered, but have not been found convincing.

Applicant submits that it is appropriate to address this issue in copending Application No. 10/813747 and file a terminal disclaimer in the '747 application, rather than address that rejection in the instant application.

Given applicant's statements concerning the applicability of the obvious double patenting rejection, it appears that applicant has acquiesced to the appropriateness of the double patenting rejection and only requests that the instant application be allowed to issue.

However, in contrast to applicant's presumptions, the instant application is not considered allowable at this time.

Therefore the double patenting rejection stands for the claims of the instant application.

15. No claim is allowed

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is 571/ 272-0840 The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/ 272-0841 .

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michail Belyavskyi, Ph.D.
Patent Examiner
Technology Center 1600
December 27, 2005

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